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Michael L. Goldman			KUBELIK, ANNE R	
NIXON PEABODY LLP Clinton Square			ART UNIT	PAPER NUMBER
P.O. Box 31051			1638	
Rochester, NY 14603			DATE MAILED: 02/13/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

'	A II AI No.	Alicent(e)			
	Application No.	Applicant(s)			
Office Action Summary	09/766,348	QIU ET AL.			
Office Action Guillinary	Examiner	Art Unit			
The MAILING DATE of this communication app	Anne R. Kubelik	1638			
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earmed patent term adjustment. See 37 CFR 1.704(b). Status					
Responsive to communication(s) filed on <u>7 Noversity</u>	vember 2003.				
2a) This action is FINAL . 2b) ⊠ This a	action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims					
4) ☐ Claim(s) 41-54 and 58-79 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 41-54 and 58-79 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.					
Application Papers					
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 					
Priority under 35 U.S.C. §§ 119 and 120					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. a) The translation of the foreign language provisional application has been received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.					
Attachment(s)					
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) attent Application (PTO-152)			

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DETAILED ACTION

- 1. In the response filed 7 November 2003, Applicant states that prior art use of one nucleic acid encoding a hypersensitive response elicitor to impart systemic acquired resistance to a plant would render obvious the use of other nucleic acids encoding other hypersensitive response elicitors (response pg 7). Therefore the restriction requirement among the groups is withdrawn and all pending claims (*i.e.*, claims 41-54 and 58-79) are examined.
- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. The rejection of claims 41-44, 49-53, 58-64, 69-73 and 75-77 under 35 U.S.C. 103(a) as being unpatentable over Bauer et al (US Patent 5,850,015, filed June 1995) in view of Wei et al (1992, Science 257:85-88) is withdrawn in light of Applicant's statement that prior art use of one nucleic acid encoding a hypersensitive response elicitor to impart systemic acquired resistance to a plant would render obvious the use of other nucleic acids encoding other hypersensitive response elicitors (response pg 7).
- 4. The objection to claims 41-44, 49-53, 62-64, 69-73 and 75 for informalities is withdrawn in light of Applicant's amendments to the claims.

Claim Objections

- 5. Claims 48, 54, 68, 74 and 78-79 are objected to because of the following informalities:

 Claims 48, 54, 68 and 74 start with an improper article.
 - In claims, line 1, there should be a comma before "wherein".

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Claim Rejections - 35 USC § 112

6. Claims 41-54 and 58-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 1 May 2003, as applied to claims 41-44, 49-53, 58-64, 69-73 and 75-77. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

Applicant urges that the specification describes four exemplary nucleic acids encoding hypersensitive response elicitors of bacterial plant pathogens and that these species are representative of the claimed genus (response pg 8).

This is not found persuasive because the instant claims are not limited to use of nucleic acids encoding hypersensitive response elicitors of bacterial plant pathogens, but include nucleic acids encoding any hypersensitive response elicitor, including from *Phytophthora*, which is a fungus. No nucleic acids encoding hypersensitive response elicitors from any *Phytophthora* or *Xanthomonas* species are described.

Applicant, referring the Declaration of Dr. Wei filed 11 February 2003, urges that the exemplary species belong to an art-recognized class of hypersensitive response elicitors that have shared properties and share the ability to induce specific plant responses, including induction of plant disease resistance, plant growth enhancement, and plant stress-resistance (response pg 8).

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This is not found persuasive because the specification only describes four such nucleic acids.

Applicant urges that in *Eli Lilly* the Federal Circuit admonished the use of functional language to describe a product, and that disclosure of only a rat cDNA encoding insulin fails to provide description for human, mammalian or vertebrate insulins (response pg 8-9).

This is not found persuasive. In the instant case the claims are drawn to use of a nucleic acid encoding a hypersensitive response elicitor from any Erwinia, Pseudomonas, Xanthomonas or Phytophthora species. The specification, however, describes only four such nucleic acids.

There are at least 12 Erwinia species, including amylovora, E. aphidicola, E. billingiae, E. carotovora, E. chrysantum, E. mallotivora, E. papayae, E. persicina, E. psidii, E. pyrifoliae, E. rhapontici, and E. tracheiphila. The instant specification only describes two nucleic acids encoding hypersensitive response elicitors from two species.

There are at least 113 Pseudomonas species, including P. abietaniphila, P. alcaligenes, P. amygdali, P. anguilliseptica, P. agarici, P. agarolyticus, P. alcaliphila, P. alginovora, P. andersonii, P. asplenii, P. aurantiaca, P. azelaica, P. azotoformans, P. balearica, P. batumici, P. borealis, P. brassicacearum, P. brenneri, P. cedrina, P. congelans, P. corrugata, P. chloritidismutans, P. chlororaphis, P. citronellolis, P. costantinii, P. cremoricolorata, P. denitrificans, P. diterpeniphila, P. extremorientalis, P. flavescens, P. filiscindens, P. fluorescens, P. fragi, P. frederiksbergensis, P. fulgida, P. jinjuensis, P. mendocina, P. nitroreducens, P. oleovorans, P. pseudoalcaligenes, P. resinovorans, P. gessardii, P. libanensis, P. mandelii, P. marginalis, P. mediterranea, P. migulae, P. mucidolens, P. orientalis, P. poae, P. rhodesiae, P.

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synxantha, P. tolaasii, P. trivialis, P. veronii, P. gingeri, P. graminis, P. grimontii, P. halodenitrificans, P. halophila, P. hibiscicola, P. hydrogenovora, P. indica, P. japonica, P. jessenii, P. kilonensis, P. koreensis, P. lini, P. lundensis, P. lurida, P. lutea, P. marginata, P. meridiana, P. palleroniana, P. parafulva, P. pavonanceae, P. pertucinogena, P. proteolytica, P. psychrophila, P. fulva, P. monteilii, P. mosselii, P. oryzihabitans, P. plecoglossicida, P. putida, P. rathonis, P. reactans, P. rhizosphaerae, P. salomonii, P. luteola, P. stutzeri, P. avellanae, P. cannabina, P. caricapapayae, P. cichorii, P. coronafaciens, P. fuscovaginae, P. syringae, P. ficuserectae, P. meliae, P. savastanoi, P. straminea, P. tremae, P. taetrolens, P. thermaerum, P. thermocarboxydovorans, P. thermotolerans, P. thivervalensis, P. umsongensis, P. vancouverensis, P. viridiflava, P. wisconsinensis, and P. xiamenensis. The instant specification only describes two nucleic acids encoding hypersensitive response elicitors from two species.

There are at least 68 Xanthomonas species, including X. albilineans, X. arboricola, X. axonopodis, X. bromi, X. campestris, X. cassavae, X. citri, X. codiaei, X. cucurbitae, X. cynarae, X. fragariae, X. gardneri, X. hortorum, X. hyacinthi, X. melonis, X. oryzae, X. pisi, X. populi, X. sacchari, X. theicola, X. translucens, X. vasicola, and X. vesicatoria. The instant specification only describes two fragments of hypersensitive response elicitors from one species.

There are at least 68 Phytophthora species, including P. arecae, P. bisheria, P. boehmeriae, P. botryosa, P. brassicae, P. cactorum, P. cajani, P. cambivora, P. capsici, P. cinnamomi, P. cinnamomi var. parvispora, P. citricola, P. citrophthora, P. clandestina, P. colocasiae, P. cryptogea, P. drechsleri, P. erythroseptica, P. europaea, P. fragariae, P. glovera, P. gonapodyides, P. heveae, P. hibernalis, P. humicola, P. idaei, P. ilicis, P. infestans, P. inflata,

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P. insolita, P. inundata, P. iranica, P. katsurae, P. kelmania, P. lateralis, P. macrochlamydospora, P. meadii, P. medicaginis, P. megakarya, P. megasperma, P. melonis, P. mirabilis, P. multivesiculata, P. nemorosa, P. nicotianae, P. palmivora, P. parasitica, P. phaseoli, P. pistaciae, P. porri, P. primulae, P. pseudosyringae, P. pseudotsugae, P. psychrophila, P. quercina, P. quininea, P. ramorum, P. richardiae, P. sinensis, P. sojae P. syringae, P. tentaculata, P. trifolii, P. tropicalis, P. uliginosa, P. undulata, and P. vignae. The instant specification only describes one nucleic acid encoding a hypersensitive response elicitor from one species.

As the majority of these species would produce at least one hypersensitive response elicitors, it is clear that the genus of nucleic acids encoding hypersensitive response elicitors within the recited genera is not fully described, and the entire genus of nucleic acids encoding hypersensitive response elicitors from any bacteria or fungus is not described. Thus, the instant specification fails to describe nucleic acids encoding hypersensitive response elicitors within the full scope of the claims, and thus fails to describe methods of using those nucleic acids.

Applicant urges that in Amgen, the Federal Circuit found that claims covering all recombinant erythropoiten non-enabled by disclosure of human and a few mutant analogs thereof; written description of diverse species within the claimed genus was lacking (response pg 9).

This is not found persuasive because, as discussed above, written description of diverse species within the claimed genus is lacking in the instant case.

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Applicant urges that the instant invention if drawn to use of nucleic acids encoding any bacterial hypersensitive response elicitor protein that, when expressed in a plant, imparts systemic pathogen resistance to the plant, and that the Wei Declaration shows that bacterial hypersensitive response elicitor proteins were an art-recognized class; furthermore, four distinct species within the genus are described (response pg 9).

This is not found persuasive because the instant specification fails to describe nucleic acids encoding hypersensitive response elicitors within the full scope of the claims, as demonstrated above.

Applicant urges that the PTO has proved no evidence as to why the four disclosed species do not adequately represent the genus, and in a footnote, states that the absence of DspE, DspF and HrpW in the prior Office action is because they were identified after the filing date of the instant application (response pg 9).

This is not found persuasive because not only is written description lacking for nucleic acids encoding hypersensitive response elicitors within the full scope of the species within the claims, as discussed above, but the citation of DspE, DspF and HrpW in the prior Office action demonstrates that even within a single species, description of only one such nucleic acids fails to describe nucleic acids encoding hypersensitive response elicitors within the full scope of the claims. That DspE, DspF and HrpW were identified only after filing of the instant application is irrelevant given the breadth of the instant claims.

7. Claims 41-54 and 58-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using nucleic acids encoding hypersensitive

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response elicitors of SEQ ID NOs:2, 4, 6 and 8 to impart pathogen resistance to plant, does not reasonably provide enablement for methods of using nucleic acids encoding any hypersensitive response elicitors to impart pathogen resistance to plant or for propagation of some plants by seed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to methods of using nucleic acids encoding hypersensitive response elicitors to impart pathogen resistance to plants.

The instant specification, however, only provides guidance for a single nucleic acid encoding a hypersensitive response elicitor of SEQ ID NOs:2, 4, 6 and 8 from each of *E. chrysanthemi*, *E. amylovora*, *Pseudomonas syringaes* and *P. solanacearum*, respectively.

The instant specification fails to provide guidance for nucleic acids encoding hypersensitive response elicitors within the full scope of the claims. The specification does not describe any nucleic acid encoding hypersensitive response elicitors from *Xanthomonas* campestris or any *Phytophthora* species or from any other *Erwinia*, *Xanthomonas* or *Pseudomonas* species.

Furthermore, the claims are drawn to the method, wherein the transgenic plants are propagated by seed. However, many of the claimed plants, including grape, pear, plum, cherry, preach, nectarine, apricot, and apple are rarely propagated by seed; commercially, these plants are instead propagated vegetatively to maintain all the traits associated with each cultivar. Seed propagation of these non-selfing plants produces plants with undesirable characteristics. The

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instant specification does not teach how to propagate these plants from seed and not lose the traits associated with the cultivars.

Given the claim breath and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

8. Claims 42-48, 52-53, 59, 61-74, 76 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 1 May 2003, as applied to claims 41-44, 49-53, 58-64, 69-73 and 75-77. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

The following rejections remain:

Claim 53 lacks antecedent basis for the limitation "the propagated plants" in line 4.

It is unclear in claims 59 and 76 if the seeds comprise the nucleic acid encoding the hypersensitive response elicitor.

Claim 61 lacks antecedent basis for the limitation "the transgenic plant". Amendment to address this rejection would also affect dependent claims.

Applicant urges that the rejection is traversed in view of amendment to the claims (response pg 9).

This is not found persuasive because the rejections above were not addressed.

The following rejections are new:

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Claims 42 and 62 are indefinite in their recitation of "and mixtures thereof". It is unclear if the protein is one from one of the listed genera that is present even when the genera are in mixtures or if the protein is one that is only present when mixtures of genera are used.

Claims 52 and 72 appear to not further limit parent claims 41 and 61, respectively. The claims are drawn to the method of imparting pathogen resistance to plants by providing plants transformed with nucleic acid encoding a hypersensitive response elicitor; however, nucleic acid encoding a hypersensitive response elicitor inherently confer resistance to viruses, bacteria, fungi and combinations thereof. If however, only some nucleic acids encoding hypersensitive response elicitor confer resistance to viruses, bacteria, fungi and combinations thereof this rejection does not apply.

Claim Rejections - 35 USC § 102

9. Claims 41-54 and 58-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Bauer et al (US Patent 5,850,015, filed June 1995). The rejection is repeated for the reasons of record as set forth in the Office action mailed 1 May 2003, as applied to claims 41-43, 49-53, 58-63, 69-73 and 75-77. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

Applicant urges that Bauer et al fails to teach or suggest each and every limitation in the claims, in particular propagating the plant from a transgenic seed, wherein the plant is characterized by systemic acquired pathogen resistance as a result of the plant expressing the hypersensitive response elicitor protein (response pg 10-11).

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This is not found persuasive because the annuals claimed by Bauer et al, including but not limited to wheat, corn, bean and lettuce, are generally propagated by seed. Thus, the claims of Bauer et al inherently read on propagation by seed.

Applicant urges that Bauer et al fails to teach or suggest transforming a plant, wherein the plant is characterized by systemic acquired pathogen resistance as a result of the plant expressing the hypersensitive response elicitor protein (response pg 11).

This is not found persuasive because the plants of Bauer et al would inherently be characterized by systemic acquired pathogen resistance as a result of the plant expressing the hypersensitive response elicitor protein. It is not necessary for Bauer et al to recognize this inherent property for the instant claims to be anticipated.

Although Bauer et al only teaches a nucleic acid encoding a hypersensitive response elicitor from *E. chrysanthemi*, this rejection is made against all the claims in light of Applicant's statement that prior art use of one nucleic acid encoding a hypersensitive response elicitor to impart systemic acquired resistance to a plant would render obvious the use of other nucleic acids encoding other hypersensitive response elicitors (response pg 7).

10. Claims 41-54 and 58-79 are rejected under 35 U.S.C. 102(e) as being anticipated by Beer et al (US Patent 6,174,717, filed July 1992). The rejection is repeated for the reasons of record as set forth in the Office action mailed 1 May 2003, as applied to claims 41-42, 44, 52, 58-62, 64, 72 and 75-77. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

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Applicant urges that Beer et al fails to teach or suggest each and every limitation in the claims, in particular propagating the plant from a transgenic seed, wherein the plant is characterized by systemic acquired pathogen resistance as a result of the plant expressing the hypersensitive response elicitor protein (response pg 11).

This is not found persuasive because many economically important annuals, including but not limited to wheat, corn, and bean, are generally propagated by seed. Thus, the Beer et al inherently teaches propagation by seed.

Applicant urges that Beer et al fails to teach or suggest transforming a plant, wherein the plant is characterized by systemic acquired pathogen resistance as a result of the plant expressing the hypersensitive response elicitor protein (response pg 11).

This is not found persuasive because the transformed plants would inherently be characterized by systemic acquired pathogen resistance as a result of the plant expressing the hypersensitive response elicitor protein. It is not necessary for Beer et al to recognize this inherent property for the instant claims to be anticipated.

Although Beer et al only teaches a nucleic acid encoding a hypersensitive response elicitor from three *Erwinia* species, this rejection is made against all the claims in light of Applicant's statement that prior art use of one nucleic acid encoding a hypersensitive response elicitor to impart systemic acquired resistance to a plant would render obvious the use of other nucleic acids encoding other hypersensitive response elicitors (response pg 7).

Double Patenting

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Claims 41-54 and 58-79 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 5,850,015. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, *e.g.*, *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). The rejection is repeated for the reasons of record as set forth in the Office action mailed 1 May 2003, as applied to claims 41-42, 44, 52, 58-62, 64, 72 and 75-77. Applicant's arguments filed 7 November 2003 have been fully considered but they are not persuasive.

Applicant urges that none of the claims of Bauer et al specify that the method is carried out by providing a transgenic seed, let alone planting it or propagating a plant therefrom wherein the plant is characterized by systemic acquired pathogen resistance as a result of the plant expressing the hypersensitive response elicitor protein (response pg 13).

This is not found persuasive because the annuals claimed by Bauer et al, including but not limited to wheat, corn, bean and lettuce, are generally propagated by seed. Propagation by seed requires "providing" the seed, planting the seed, and propagating a plant therefrom. Thus, the claims of Bauer et al inherently read on propagation by seed.

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Applicant urges that the claims of Bauer et al are limited to use of a pathogen inducible promoter, while the claimed invention involves systemic pathogen resistance, not inducible pathogen resistance (response pg 13).

This is not found persuasive because the plant of claim 9 does not have the limitation of a pathogen inducible promoter. Furthermore, once a pathogen inducible promoter is induced, the pathogen resistance conferred by the nucleic acid encoding the hypersensitive response elicitor is systemic.

Conclusion

- 12. No claim is allowed.
- 13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D. February 2, 2004

Jane Holdle